Ranbaxy (M) Sdn Bhd v EI Du Pont Nemours and Co

COURT OF APPEAL (PUTRAJAYA) — CIVIL APPEAL NO W-02–533 OF 2011
RAMLY ALI, CLEMENT SKINNER AND MOHTARUDIN BAKI JJCA
8 MARCH 2012

Patents — Disclosure — Sufficiency of disclosure — Application to invalidate claims on ground disclosure insufficient and unclear to be understood and performed by person having ordinary skill in the art — Allegation that patent description did not support claims — Whether description contained statement of invention's advantages with reference to background art — Whether respondent's failure to testify at trial fatally affected its case

The appellant made and distributed pharmaceutical products, among which was a drug known as COVANCE that contained losartan potassium as its active ingredient. COVANCE was the generic equivalent of the 414 invention ('the patent') which was owned and patented by the American-based respondent company and used in the making of its drug, COZAAR. The appellant brought an action against the respondent in the High Court to invalidate claims 7 and 8 out of the 29 claims in the patent. These two claims concerned the manner of producing losartan potassium salt in crystalline form used in the treatment of hypertension and congestive heart failure. The appellant also sought a declaration that COVANCE did not infringe claims 7 and 8. The respondent counterclaimed that the appellant, to whom it had not granted any rights under the patent, had infringed claims 7 and 8 as COVANCE contained losartan potassium in crystalline form. The High Court dismissed the appellant's claim with costs and allowed the counterclaim with costs besides granting orders against the appellant for an injunction, delivery up, disclosure and/or destruction of all infringing products, discovery of all documents relating to the appellant's manufacture, supply, distribution and sales of the infringing product and an inquiry as to damages and costs. The appellant appealed to the Court of Appeal against the whole of the High Court's decision but at the hearing restricted its appeal to only two grounds: (i) that the High Court wrongly held that the respondent was properly before the court defending the action when, in fact, it did not appear in court either to defend the action or to prosecute the counterclaim and (ii) that the High Court erred in holding claims 7 and 8 of the patent were valid and enforceable against third parties. As to this second ground of appeal, the appellant argued that claims 7 and 8 were invalid and unenforceable as they failed to comply with the Patents Act 1983 and the Patents Regulations 1986 ('Regulations') in that the information disclosed in those claims were inadequate, unclear and incomplete for the invention to be understood, evaluated and carried out by a person

having ordinary skill in the art. There was also no statement of what advantageous effects the invention had with reference to the background art. It was further contended that the patent's description failed to describe and teach the invention fully and support the claims.

Held, dismissing the appeal with costs and affirming the High Court's decision:

(1) Claims 7 and 8 of the patent were at all material times valid and subsisting and therefore were enforceable against any third party including the appellant (see para 66).

(2) The disclosure in Example 316 Part D ('example') in respect of claim 7 of the specification was sufficient to enable a person of ordinary skill in the art to produce crystalline losartan potassium. The example gave unmistakable indication as to the predictability of success. The method disclosed by the example inherently produced the crystalline form of losartan potassium. Such disclosure clearly complied with the requirements of regs 12(1)(c) and 13(1) of the 1986 Regulations (see paras 43 & 47).

(3) The trial judge correctly accepted the findings of DW6 and DW7 as true and accurate. They were persons skilled in the art. Their experiments, which followed the teaching in example found within the patent's description, rebutted the appellant's allegation that claims 7 and 8 were not supported by the description. There was no evidence from any other expert to challenge or contradict their findings (see para 42).

(4) The advantageous effects of the invention with reference to the background art had been set out in various parts of the patent's description. Thus the requirement in reg 12(1)(c) had been fulfilled (see para 45).

(5) The description in claim 8 of the patent sufficiently and adequately described or taught the invention and supported the invention. No evidence was adduced by the appellant to rebut the finding on this issue (see para 56).

(6) There was no law to say a party to a civil proceeding must personally attend court and testify to support its claim or counterclaim. The totality of the evidence from all seven witnesses for the respondent and the documents tendered on its behalf enabled the respondent to establish both its defence to the claim and its case in the counterclaim. The fact that the respondent's own representative did not attend court to testify personally was not in any way fatal to the respondent's case (see paras 71 & 73).

[Bahasa Malaysia summary

Perayu membuat dan mengagihkan barangan farmaseutikal, antaranya adalah dadah yang dikenali sebagai COVANCE yang mengandungi *losartan potassium* sebagai bahan aktifnya. COVANCE adalah bersamaan generik 414 ciptaan ('paten') yang dimiliki dan dipatenkan oleh syarikat responden dari Amerika Syarikat dan digunakan dalam membuat ubatnya, COZAAR. Perayu membawa tindakan ini terhadap responden di Mahkamah Tinggi untuk mentaksahkan tuntutan-tuntutan 7 dan 8 daripada 29 tuntutan di dalam paten tersebut. Kedua-dua tuntutan ini adalah mengenai cara mengeluarkan *losartan potassium salt* dalam bentuk kristal yang digunakan di dalam perawatan hipertensi dan kegagalan jantung kongestif. Perayu juga memohon perisytiharan bahawa COVANCE tidak melanggar tuntutan-tuntutan 7 dan 8. Responden menuntut balas bahawa perayu, yang tidak diberikan apa-apa hak di bawah paten, telah melanggar tuntutan-tuntutan 7 dan 8 memandangkan COVANCE mengandungi *losartan potassium* dalam bentuk kristal. Mahkamah Tinggi menolak tuntutan perayu dengan kos dan membenarkan tuntutan balas dengan kos disamping memberikan perintah-perintah terhadap perayu untuk injunksi, penyampaian, pendedahan dan/atau pembinasaan kesemua barangan 'infringing', penemuan kesemua dokumen berkaitan perkilangan perayu, pembekalan, pengagihan dan jualan barangan 'infringing' dan siasatan terhadap ganti rugi dan kos. Perayu merayu ke Mahkamah Rayuan terhadap kesemua keputusan Mahkamah Tinggi tetapi pada masa pendengaran menghadkan rayuannya hanya kepada dua alasan: (i) bahawa Mahkamah Tinggi secara salah memutuskan bahawa responden dengan betul di hadapan mahkamah membela tindakan tersebut apabila sebenarnya ia tidak hadir di mahkamah sama ada untuk membela tindakan tersebut atau untuk mendakwa tuntutan balas dan (ii) bahawa Mahkamah Tinggi tersilap dalam memutuskan tuntutan-tuntutan 7 dan 8 paten adalah sah dan berkuat kuasa terhadap pihak ketiga. Mengenai alasan kedua rayuan ini, perayu berhujah bahawa tuntutan-tuntutan 7 dan 8 tidak sah dan tidak berkuat kuasa kerana ia gagal untuk mematuhi Akta Paten 1983 dan Peraturan-Peraturan Paten 1986 ('Peraturan-Peraturan') di mana maklumat yang dikemukakan dalam tuntutan-tuntutan tersebut tidak mencukupi, tidak jelas dan tidak lengkap untuk ciptaan difahami, dinilaikan dan dilaksanakan oleh seseorang yang mempunyai kemahiran biasa di dalam seni tersebut. Juga tidak terdapat penyataan mengenai apa kesan-kesan kelebihan yang dimiliki ciptaan dengan rujukan kepada seni latar belakang. Ia selanjutnya dihujahkan bahawa deskripsi paten gagal untuk menerangkan dan mengajar sepenuhnya tentang ciptaan dan menyokong tuntutan-tuntutan tersebut.

Diputuskan, menolak rayuan dengan kos dan mengesahkan keputusan Mahkamah Tinggi:

(1) Tuntutan-tuntutan 7 dan 8 paten pada kesemua masa material sah dan

wujud dan oleh itu berkuat kuasa terhadap mana-mana pihak ketiga termasuk perayu (lihat perenggan 66).

(2) Pendedahan di dalam Example 316 Part D ('example') berkaitan tuntutan 7 spesifikasi adalah mencukupi untuk membolehkan seseorang yang mepunyai kemahiran biasa dalam seni untuk mengeluarkan kristal *losartan potassium. Example* telah menunjukkan tanda jelas terhadap kebolehramalan kejayaan tersebut. Cara yang didedahkan oleh *example* sememangnya mengeluarkan bentuk kristal *losartan potassium*. Pendedahan sedemikian jelas mematuhi dengan keperluan peraturan-peraturan 12(1)(c) dan 13(1) Peraturan-Peraturan (lihat perenggan 43 & 47).

(3) Hakim perbicaraan dengan betul menerima dapatan DW6 dan DW7 sebagai benar dan tepat. Mereka adalah orang yang mahir dalam seni tersebut. Eksperimen mereka, yang mengikuti penjelasan dalam *example* yang didapati dalam deskripsi paten, mematahkan dakwaan perayu bahawa tuntutan-tuntutan 7 dan 8 tidak disokong oleh deskripsi. Tidak terdapat keterangan daripada mana-mana pakar untuk mencabar atau menyangkal dapatan-dapatan mereka (lihat perenggan 42).

(4) Kesan-kesan kelebihan ciptaan dengan rujukan kepada seni latar belakang telah dijelaskan di dalam pelbagai bahagian deskripsi paten. Oleh itu keperluan dalam peraturan 12(1)(c) telah dipenuhi (lihat perenggan 45).

(5) Deskripsi dalam tuntutan 8 paten dengan mencukupi dan memadai menjelaskan atau mengajar mengenai ciptaan dan menyokong ciptaan. Tiada keterangan yang dikemukakan oleh perayu untuk mematahkan dapatan atas isu ini (lihat perenggan 56).

(6) Tidak terdapat undang-undang untuk menyatakan pihak kepada prosiding sivil mesti dengan sendiri menghadiri mahkamah dan memberi keterangan untuk menyokong tuntutannya atau tuntutan balas. Keseluruhan keterangan daripada kesemua tujuh saksi untuk responden dan dokumen-dokumen yang diserahkan bagi pihaknya membolehkan responden membuktikan kedua-dua pembelaannya kepada tuntutan dan kesnya did alam tuntutan balas. Fakta bahawa wakil peribadi responden tidak hadir di mahkamah untuk memberi keterangan dengan sendiri tidak dalam apa cara sekalipun memudaratkan kes responden (lihat perenggan 71 & 73).]

Notes

For a case on sufficiency of disclosure, see 10 *Mallal's Digest* (4th Ed, 2011 Reissue) para 1169.

Cases referred to

Asahi Kasei Kogyo KK's Application [1991] RPC 485, HL (refd)
Catnic Components Ltd and another v Hill and Smith Limited [1982] RPC 183, HL (refd)
General Tire & Rubber Company, The v Firestone Tyre and Rubber Company Limited and others [1972] RPC 457, CA (refd)
Generics (UK) Ltd and others v H Lundbeck A/S [2009] All ER 963, HL (refd)
Heveafoam Asia Sdn Bhd v PF (Teknologi) Sdn Bhd [2001] 2 MLJ 660, HC (refd)
Kirin-Amgen v Hoescht Marion Roussel Ltd [2004] All ER (D) 286, HL (refd)
Lilly Icos Ltd v Pfizer Ltd [2000] EWHC Patents 49; [2000] 35 BMLR 123 (refd)
Lubrizol Corpn v Esso Petroleum Co Ltd [1998] RPC 727, CA (refd)
Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd [1996] RPC 76, HL (refd)
Rockwater v Technip France SA and another [2004] RPC 919, CA (refd)
Synthon BV v Smithkline Beecham plc [2006] 1 All ER 685, HL (refd)

Legislation referred to

Evidence Act 1950 ss 101, 118, 120(1), 134
Patents Act 1977 [UK] s 14(3), (5)
Patents Act 1983 ss 11, 14(2), 23, 29A, 29A(2), (4), 30, 30(1), 56(2)(b), 87
Patents Regulations 1986 regs 12(1)(c), 13(1), 27A

Appeal from: Civil Suit No D5(IP)–22–16 of 2009 (High Court, Kuala Lumpur)

Harpal Singh Grewal (Azura Adnan, Arlene Tan Eng Guan, Remy Rao and Nik Ahmad Asraf Nik Othman with him) (Miranda & Samuel) for the appellant.
SF Wong (Zaraihan Shaari and CY Loi with him) (Shearn Delamore & Co) for the respondent.

Ramly Ali JCA (delivering judgment of the court):

[1] The appellant/plaintiff, Ranbaxy (M) Sdn Bhd is a company incorporated in Malaysia and is involved in a business of manufacturing and distributing pharmaceutical products in particular the manufacturing and distribution of pills commercially known as COVANCE containing an active pharmaceutical ingredient losartan potassium (the corresponding generic of the 414 invention). The appellant has obtained regulatory approval from the National Pharmaceutical Control Bureau ('NPCB') for COVANCE tablet 25mg, 50mg and 100mg in Malaysia.

[2] The respondent/defendant, EI Du Pont De Nemours and Co is a

company incorporated in the United States of America. It is the proprietor of the 414 patent; it carries on business as, inter alia, a manufacturer, distributor and exporter of a wide range of chemical and other products.

[3] The subject matter in the present case is the MY-110414-A patent entitled 'Angiotensin II Receptor Blocking Imidazoles and Combinations thereof with Diuretics and Nsaids' (the 414 patent), which was filed on 6 January 1989. At the High Court, the 414 patent was challenged by the appellant on various grounds of validity, in particular the validity of its claims 7 and 8. The appellant's case against the respondent is that claims 7 and 8 of the 414 patent are invalid and hence, are unenforceable against any third party. The appellant is also seeking for a declaration that its COVANCE products with the active pharmaceutical ingredient losartan potassium, do not infringe claims 7 and 8 of the 414 patent. The appellant claimed that it has obtained regulatory approval from NCPB for the sale of COVANCE and therefore the manufacturing and sale of COVANCE products do not constitute an infringement of the 414 patent.

[4] The respondent on the other hand, has counterclaimed that the appellant has infringed claims 7 and 8 of the 414 patent wherein the appellant's products COVANCE contain losartan potassium in crystalline form.

[5] At the High Court, after full hearing, the learned judge dismissed the appellant's claim with costs and allowed the respondent's counterclaim with costs. The learned judge also made the following orders:

(a) an injunction to restrain the plaintiff/appellant whether by itself, its directors, officers, employees, servants or agents or any of them howsoever:

(i) from infringing the defendant's 414 patent by manufacturing, supplying, distributing, selling or offering for sales its COVANCE products whether or not of 50 mg and 100 mg or any other products of whatsoever brand that contain losartan potassium in crystalline form; and

(ii) causing, enabling, facilitating, abetting or assisting any others include AA Pharmacy Sdn Bhd to infringe the defendant's 414 patent by manufacturing and supplying to them for onward supplies or sales to the doctors and the public, COVANCE products whether or not of 50mg and 100mg or any other branded products containing losartan potassium in crystalline form;

(b) an order for delivery up, disclosure and/or destruction upon oath all the plaintiffs infringing products containing losartan potassium in crystalline form whether under the COVANCE or any other brand;

(c) an order for full discovery (which the plaintiff shall comply within 14 days of the order if granted) of all relevant documents, contracts, purchase orders, delivery orders, invoices, receipts and all other relevant documents relating to the plaintiff's manufacture, supply, distribution and sales of their COVANCE or other products containing losartan potassium in crystalline form in the possession, power, custody or control of the plaintiff, its directors, servants or agents;

(d) an enquiry as to damages suffered by the defendant or alternatively at the defendant's option, an account of profits made by the plaintiff derived from its acts of infringement and or causing the infringement of the defendant's 414 patent; and

(e) an order that the plaintiff by its directors, officers, employees, servants or agents recall from the market including from the doctors, pharmacies and or hospitals to whom the plaintiff has supplied or sold its infringing COVANCE or other products that contain losartan potassium in crystalline form.

THE PRESENT APPEAL

[6] Being dissatisfied with the above decision, the appellant then filed an appeal to the Court of Appeal. In essence, the appellant's appeal before us is against the whole of the High Court's decision dismissing both their invalidity claim against the respondent's 414 patent, and declaration of non-infringement of its COVANCE 25mg, 50mg and 100mg as against claims 7 and 8 of the 414 patent; as well as against the decision allowing the respondent's counterclaim for infringement of the 414 patent.

[7] At the hearing of the appeal before us, learned counsel for the appellant informed the court that the appeal is based on two grounds, namely:

(a) procedural issue ie the respondent ('EI Du Pont De Nemours') did not appear in court either to defend the action or to prosecute the counterclaim; and

(b) invalidity of the 414 patent ie claims 7 and 8 are invalid and therefore the 414 patent is also invalid and unenforceable against any other party.

THE APPELLANT'S CASE

[8] As regard to the first ground, the appellant complained that the respondent (EI Du Pont De Nemours) was not physically present in court to

give testimony before the learned judge during trial; and also there was no representative from the respondent company in court during trial. According to the appellant in truth the party defending the action was Merck & Co, without applying to add itself as a party to the suit. The appellant submitted that the learned judge had erred in law or in fact when His Lordship held that the respondent (EI Du Pont Nemours) was properly before the court defending the action.

[9] The appellant further contended that, on evidence it was clear that EI Du Pont Nemours did not appear either to defend the action or to prosecute the counterclaim. In fact, the appellant alleged that every witness called by the defence said that he had been instructed by Merck to do whatever he did. The appellant also questioned the authority of the solicitors acting for the respondent in the trial, on the ground the said solicitors may have been appointed by Merck, not by the respondent. The appellant further submitted that the respondent's defence and counterclaim should have been dismissed by the High Court, on this ground alone.

[10] On the validity of claim 7 of the 414 patent, the appellant contended that claim 7, was invalid and unenforceable on the ground that, it did not disclose the respondent's invention in such terms that it can be understood and in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skill in the art and state any advantageous effect of the invention with reference to the background art. The appellant submitted that the learned judge erred in holding that the disclosure in Example 316 Part D of the 414 patent is sufficient to enable a person of ordinary skill in the art to produce crystalline losartan potassium even though the said example does not expressly state that the crystalline form would be produced. The appellant claimed that the method of preparing and obtaining losartan and potassium in crystalline form was not disclosed in Example 316 Part D; and it should have been described in a clear and complete manner in Example 316 Part D of the 414 patent.

[11] As regard to claim 8 of the 414 patent, the appellant contended that claim 8, which relates to the compound of losartan and hydrochlorothiaside ('HCT') is unsupported by any of the description in the said patent nor does the said patent provide any examples vis-a-vis the invention to teach and enable the public to use the teaching of the patent document to practice the invention in as ample and beneficial a way as the patentee himself uses it. Therefore, the appellant argued that the respondent has failed to comply with ss 23 and 30 of the Patents Act 1983 as well as reg 27A of the Patents Regulations 1986 (the 1986 Regulations); and consequently the said claim 8 is invalid and

unenforceable.

THE RESPONDENT'S CASE

[12] The respondent is the owner of the 414 patent which is validly subsisting. In Malaysia the respondent and/or its licensees, Merck & Co Inc markets the said products by claim 7 of the patent using trade name COZAAR. The respondent claimed that the appellant's generic losartan products known as COVANCE infringes claim 7 of the 414 patent. The respondent did not grant any rights to which it is entitled under the 414 patent to the appellant; and therefore the appellant is not entitled to manufacture, supply and/or sell the said COVANCE product in the absence of any authorisation from the respondent despite the NPCB's confirmation or license that it had complied with the necessary requirements for the purpose of drug registration. For these reasons, the respondent counterclaimed against the appellant for, inter alia, injunction, an order for delivery up, disclosure and/or destruction, an order for full discovery and an inquiry as to damages and costs.

[13] On the procedural issue of the respondent not defending the action and not prosecuting its counterclaim, by not being present in court during trial, the respondent stressed that it has called seven witnesses and tendered numerous exhibits to defend the validity of the 414 patent and to prove its counter claim for infringement against the appellant. The respondent argued that it has a complete discretion as to the preference and selection of the witnesses to be called at the trial and the documents to be produced to prove all facts essential to its case; therefore it matters not if the representative of the respondent was or was not present in court during the course of trial.

[14] On the issue of validity of claims 7 and 8 as challenged by the appellant, the respondent maintained that the unrebutted evidence adduced by the respondent's witnesses and documents tendered clearly proved that the information disclosed in Example 316 Part D of the 414 patent was sufficiently clear and complete to enable a person of ordinary skill in the art to evaluate and carry out the invention being claimed in claim 7 of the 414 patent. As regard to claim 8 of the same 414 patent, the respondent maintained that the description of the 414 patent sufficiently and adequately describes and teaches the invention fully within the specification and supports the invention as claimed in claim 8. The respondent submitted that the appellant at the High Court hearing did not rebut the respondent's submission on the sufficiency of support for claim 8.

FINDINGS OF THIS COURT

Validity of the 414 patent: claims 7 and 8

[15] The patent application for the 414 patent was filed on 6 January 1989

claiming priority of US142.580 (application date — 7 January 1988) and US279.194 (application date — 6 December 1988). Therefore earliest priority date ie 7 January 1988 (the filing date of Patent No 142580 is therefore the priority date of the 414 patent). For the purpose of invalidation, any prior disclosure or prior use relied upon must be those that were already available to the public before this date (7 January 1988), as stipulated under s 14(2) of the Patent Act 1983. At the material time, the 414 patent consists of claims 1–29. It was published and granted on 30 May 1998 and due to expire on 29 May 2013, subject to a payment of annual renewal fee. In the present suit, only two claims are in issue, ie claims 7 and 8. These two claims concerned the substituted imidasoles called losartan potassium salt in crystalline form; these chemical compounds have activity for treating hypertension and congestive heart failure. These are the only two claims that the appellant sought to invalidate. Both claims 7 and 8 are independent claims.

[16] Claim 7 is directed to the chemical compound of salt of losartan in the form of losartan potassium, in its crystalline form. Claim 8 relates to pharmaceutical composition comprising a pharmaceutically suitable carrier, losartan or hydrochlorothiaside. The losartan salt in the said pharmaceutical composition may be, though not necessarily, in the form of losartan potassium, whether or not in its crystalline form.

[17] The appellant's challenge on the validity of the 414 patent in premised on the grounds:

(a) that the 414 patent specifications do not sufficiently and fairly describe the said claims 7 and 8, and the methods by which the inventions claimed in the claims are to be performed; and

(b) that claims 7 and 8 of the 414 patent do not comply with the provisions of ss 23 and 30 of the Patents Act 1983 as well as reg 27A of the Patents Regulations 1986.

[18] The appellant submitted that the disclosure of information in relation to claim 7 is hopelessly inadequate and clearly does not meet the requirements of s 23 of the Patents Act 1983 that requires an invention to be described in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skill in the art. The appellant also claimed that claim 7 does not comply with reg 12(1) of the 1986 Regulations as it does not disclose the invention in such terms that can be understood and in a manner sufficiently clear and complete for the innovation to be evaluated and to be carried out by a person having ordinary skill in the art.

[19] With regard to claim 7, Example 316 Part D of the 414 patent reads:

PART D: Preparation of 2'butyi-4-chioro-5-hyroxy-methyl-l-l (2'-(1H-tetrazol-5-vl)-biDhenvl'4-vDmethvnimidizole: potassium salt. The product of Part C (11.00 g) and isopropanol (30 ml) was charged to a 100 ml round-bottomed flask equipped with magnetic stirrer, thermometer and Dean stark trap under nitrogen. The slurry was heated to 40° C. A solution of 87% potassium hydroxide (2.00 g)/isopropanol (20 ml/water (1.0 ml) was added to pl-l 11 (18.5 ml). Most of the water was removed by azeotropic distillation of isopropanol (20 ml distilled). Hieptane (25 ml) was added and the slurry cooled to room temperature. Additional heptanes (15 ml) were added and the mixture stirred for 1A hr. The product was isolated by vacuum filtration, washed 1/2 ml heptanes and dried overnight at 60° C in vacuo. Yield: 10.33 g 86% M.P. > 250° C.

[20] Claim 8 of the 414 patent reads:

A pharmaceutical composition comprising a pharmaceutical suitable earner with a combination of 2-butyl-4-chloro-1-(2' (1 H-tetrazol'5-yl) (biphenyl-4-yl) (methyl)'5-hydroxymenthyl) imidizole or a pharmaceutical acceptable salt thereof, and hydrochlorothiazide.

[21] Under s 56(2)(b) of the Patents Act 1983, the court shall invalidate the patent if the person requesting the invalidation proves that the description or the claim does not comply with the requirements of s 23 of the Act. Section 23, provides that every application for the grant of a patent shall comply with the regulations as maybe prescribed by the Minister under the Act. The relevant Minister is empowered to make regulations in the exercise of the powers conferred by s 87 of the Act; and in the exercise of that powers, the Minister made the 1986 Regulations.

[22] Regulation 12(1)(c) of the 1986 Regulations provides that 'the description shall first state the title of the invention as appearing in the request and shall disclose the invention in such terms that it can be understood and in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skill in the art, and state any advantageous effect of the invention with reference to the background art'.

[23] Regulation 13(1) of the 1986 Regulations provides, inter alia, that 'the claims shall be clear and concise and fully supported by the description; and the number of claims shall be reasonable taking into consideration the nature of the invention'.

[24] In short, the court may invalidate the patent, if there is non-compliance of reg 12(1)(c) or reg 13(1) of the 1986 Regulations.

[25] The provisions of reg 12(1)(c) of the 1986 Regulations has similar

wordings to those in s 14(3) of the UK Patents Act 1977 and art 83 of the European Patents Convention ('EPC'). The provisions of reg 13(1) of the 1986 Regulations has similar wordings to those in s 14(5)(c) of the UK Patents Act 1977 and art 84 of the European Patents Convention (EPC).

[26] Both regs 12(1)(c) and 13(1) of the 1986 Regulations are intended to be mutually dependent with one another. Therefore, the court has to look at the description part of the specifications of the 414 patents to ascertain if it discloses the invention sufficiently and in a clear and complete manner to support the claims found in the 414 patent.

[27] In the House of Lords' case of *Generics (UK) Ltd and others v H Lundbeck A/S* [2009] All ER 963, Lord Walker referred to a previous House of Lords' case of *Asahi Kasei Kogyo KK's Application* [1991] RPC 485 and took the view that the requirements of the UK's sufficiency provision, ie s 14(3) of the Patents Act 1977 is one that takes into account the requirement laid out in its s 14(5). Lord Walker went on to say:

> There is therefore high authority that the requirements of s 14(3) and s 14(5) are closely connected. The main difference between them is that s 14(3) relates to the specification as a whole, whereas s 14(5)(c) relates to the claims which define the monopoly sought by the inventor ….
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> Lord Walker further said:
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> Section 14(3) and (5)(c) operate together, as EPC articles 83 and 84 operate together, to spell out the need for an 'enabling disclosure', which is central to the law of patents. … The disclosure must be such as to enable the invention to be performed (that is, to be carried out if it is a process, or to be made if it is a product) to the full extent of the claims. The question whether there is sufficient enabling disclosure often interacts with a question of construction as to the extent of the claims.
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> (See also *Asahi Kasie Kogyo KK's Application*; *Biogen Inc v Medeva plc* [1996] 38 BMLR 149; [1997] RPC 1; and *Kirin-Amgen Inc v Hoechst Marion Rousel Ltd* [2004] All ER (D) 286).

[28] Owing to the similar wordings used in regs 12(1)(c) and 13(1) of the 1986 Regulations, we are of the view that the approach taken by the House of Lords in the above mentioned cases is equally applicable to the present case. Applying the above principle to the facts of the present case and the wordings of reg 12(1)(c) it is clear that the description in the patient specifications of the 414 patent, would be required by law to comply with the relevant regulations.

[29] Regulation 12(1)(c) of the 1986 Regulations mentions about 'a person having ordinary skill in the art'. The disclosure requirement under the said

regulation must be sufficiently clear and complete for the invention to be evaluated and to be carried out by 'a person having ordinary skill in the art'. Lord Hoffman in *Kirin-Amgen v Hoescht Marion Roussel Ltd* [2004] All ER (D) 286 said:

> In the case of a patent specification the notional addressee is the person skilled in the art. He (I say once and for all, she) comes to a reading of the specification with common general knowledge of the art.

[30] On the same subject, Adous J explained in the case *Lubrizol Corpn v Esso Petroleum Co Ltd* [1998] RPC 727, as follows:

> Patent specifications (description) are intended to be read by persons skilled in the relevant art, but their construction is for the court. Thus, the court must adopt the mantle of the notional skilled addressee and determine, from the language used, what the notional skilled addressee would understand to be the ambit of the claim. To do that it is often necessary for the court to be informed as to the meaning of technical words and phrases and what was, at the relevant time, the common general knowledge; the knowledge that the notional skilled man would have.

[31] The issue was also enlightened by Lord Jacob LJ in *Rockwater v Technip France SA and another* [2004] RPC 919 in the following words:

> The 'man skilled in the art' is invoked at many critical points of patent law. The claims of a patent must be understood as if read by that notional man — in the hackneyed but convenient phrase the court 'must don the mantle of the skilled man'.

[32] The publication and the patentee's claim must each be construed as they would be at the respective relevant dates by a reader skilled in the art to which they relate, having regard to the state of knowledge in such art at the relevant date. The construction of these documents is a function of the court, being a matter of law, but, since documents of this nature are almost certain to contain technical material, the court must, by evidence, be put in the position of a person of the kind to whom the document is addressed, that is to say, a person skilled in the relevant art at the relevant date.

(See *The General Tire & Rubber Company v Firestone Tyre and Rubber Company Limited and others* [1972] RPC 457; and *Heveafoam Asia Sdn Bhd v PF (Teknologi) Sdn Bhd* [2001] 2 MLJ 660).

[33] On this issue, we are in full agreement with the learned High Court judge in the present case when His Lordship said:

> Thus, this court needs the assistance of the notional skilled person in determining from the technical and scientific language used in the 414 patent documents, the ambit of claims 7 and 8 and the relevant descriptions. The court requires being

knowledgeable of the implication of technical descriptions and terms and what the common general knowledge is at the material time. However, at the end of the day, all questions in connection with the interpretation of the claim and specification of the 414 patent must be resolved by this court. It is for the court to come to a decision on the matter of construction.

[34] The present case is one where the appellant has alleged that the respondent's 414 patent is invalid. The defence pled by the respondent is such that the presence and views of persons skilled in the art are necessarily required to defend the 414 patent. The nature of an invalidity case turns on the reading of the relevant subject patent claims and cited prior documents. It is the views of the persons skilled in the art that are important and one which would have bearing on the interpretation and construction of the relevant claims and prior art documents. These persons skilled in the art would have to be those with the requisite experience in the relevant field of technology and one who are independent enough for their views to be taken with sufficient weightage and due regard by the court.

[35] The importance of the views of the persons skilled in the art in the interpretation of any relevant subject claims and cited prior arts was stressed by Laddie J in the case of *Lilly Icos Ltd v Pfizer* [2000] EWHC Patents 49;; [2000] 35 BMLR 123 as follows:

> The question of obviousness has to be assessed through the eyes of the skilled but non-inventive man in the art. This is not a real person. He is a legal creation. He is not supposed to offer an objective test of whether a particular development can be protected by a patent. He is deemed to have looked at and read publicly available documents and to know of public uses in the prior art. He understands all language and dialects. He never misses the obvious nor stumbles on the inventive. He differs from all real people in one or more of these characteristics.

[36] At p 145 of the same case, His Lordship continued:

> Likewise, evidence that ordinary men in the art and working from the same prior art at the relevant time independently came to the same development may be some evidence that the notional skilled man would have done likewise. However, the evidence is rarely that simple. In most substantial patent cases the technology at issue is sophisticated and the witnesses called are experts in their fields. In most cases, of which this is a good example, they are either renowned academics or researches who have been immersed in the research and development departments of major companies. In either case, they come to the issues not only with a profound understanding of the technology but also frequently with knowledge of additional private and relevant information which is not deemed to be known to the notional addressee. This is all material of which the notional skilled in the art will be ignorant of.

[37] In the present case, the respondent had called seven witnesses to testify on its behalf to prove its defence and counterclaim. DW6 and DW7 were called to satisfy the requirement of 'persons skilled in the art' as required under reg 12(1)(c) and reg 13(1) of the 1980 Regulations. A

[38] DW6 ('Prof Jo Klaveness') holds the positions of CEO and President of Drug Discovery Laboratory AS, Oslo, Norway; CEO of DDL Biopharma AS, Oslo, Norway and Professor in Medicinal Chemistry (School of Pharmacy), University of Oslo. Furthermore DW6 has for several years been involved as a scientific expert in various legal cases in Norway and Finland concerning losartan potassium. DW6's job functions involve the synthesis of active pharmaceutical ingredients and XRD analysis of XRD patterns of substance containing the said ingredients. He testified to having carried out the method disclosed by Example 316 Part D of the US5,138,069 (which is identical to Example 316 Part D of the 414 patent) 11 different times. Out of these eleven experiments, nine were carried out with minor variations but within the parameters of said Example 316 Part D. Two experiments were performed exactly as described in Example 316 Part D without any variations. The experiments were conducted to show that one (a person skilled in the art) would obtain losartan potassium in crystalline form (in claimed invention) and thus rebuts the appellant's sufficiency argument. It is DW6's testimony that the specifications of the 414 patent, when read together as a whole, suggests to a person skilled in the art that the crystalline form of losartan potassium can be made. In other words, any person of ordinary skill in the art would find that the disclosure in the 414 patent specifications, particularly, the method disclosed by Example 316 Part D is sufficient to enable him to produce crystalline losartan potassium in claim 7. Such disclosure clearly complies with the requirement of reg 12(1)(c) and reg 13(1) of the 1986 Regulations. B C D E F

[39] DW7 ('Len Chyall'), who is a director at the SSCI division of Aptuit, also performed the exact evidence as DW6 in his laboratory at Aptuit. He had given evidence to the effect that all the three experiments that were performed by him were carried out in exactly the same manner as Example 316 Part D instructs, save for the first experiment where he had used 85% instead of 87% KOH. In all the three experiments, he testified to having obtained losartan potassium in crystalline form. G H

[40] The credentials of DW7 can be gained from his job functions which include the development of new products (primarily pharmaceuticals), as well as his experience in the field of analytical chemical involving XRD and NMR spectroscopy. I

[41] Both DW6 and DW7's evidence were important to rebut the appellant's allegation that claims 7 and 8 of the 414 patent were not supported by the

description of the patent. The experiments conducted by both DW6 and DW7 which followed the teaching of Example 316 Part D found within the description proved otherwise. Their evidence has enlightened the court on the special meaning of technical and scientific terms used in the description of the 414 patent specifications and on the common general knowledge of the art relating to the issue at hand.

[42] The court is satisfied that both DW6 and DW7 are persons skilled in the art and persons having a practical interest in the subject matter of the invention. Both of them are persons with practical knowledge and experience of the kind of work in which the invention was indeed used (see decision of Lord Diplock in the case of *Catnic Components Ltd and another v Hill and Smith Limited* [1982] RPC 183). There is no evidence from other expert to challenge or contradict DW6's findings. The learned trial judge was correct when His Lordship accepted DW6's findings as true and accurate. The same applies to DW7. He is a qualified and experienced expert in this field. His evidence is not contradicted by other expert. The learned trial judge was not wrong in accepting DW7's testimony as true and accurate.

[43] The disclosure in Example 316 Part D in respect of claim 7 of the 414 patent specifications is sufficient to enable a person of ordinary skill in the art to produce crystalline losartan potassium even though the example does not expressly state that the crystalline form of losartan potassium would be produced. The example gives unmistakable indication as to the predictability of success. The method disclosed by Example 316 Part D inherently produces the crystalline form of losartan potassium.

[44] The test of inherent disclosure in the patent's specification would be sufficient for the purpose of the description. The disclosure is sufficient to show that the natural result following from the operation as taught would result in the performance of the questioned function. It is well settled that the disclosure of this nature should be regarded as sufficient for its purpose (see *Re Oelrich*, 666 F 2d 578, 581 (CCPA 1981); *Synthon BV v Smithkline Beecham plc* [2006] 1 All ER 685 and *Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd* [1996] RPC 76).

[45] The second limb of reg 12(1)(c) of the 1986 Regulations requires that the description shall 'state any advantageous effects of the invention with reference to the background art'. In the case before us we are satisfied that the advantageous effects of the invention have been set out in various part of the description of the 414 patent. Example of statements in the description which highlight the advantageous effect of the invention with reference to the background art are:

(a) 'administration of a compound of this invention with a non-steroidal

anti-inflammatory drug (NSAID) can prevent renal failure which sometimes results from administration of a NSAID' (in lines 31-33 page 1 of the MY 414 Patent specification); and

(b) 'non-steroidal anti-inflammatory drugs (NSAID) have been reported to induce renal failure in patients … administration of an all blocking compound of this invention in combination with an NSAID … can prevent such renal failure' (in lines 20–26 on page 5 of the MY 414 Patent specification).

Therefore, the requirement as to 'the advantageous effects' under the said reg 12(1)(c) has been fulfilled.

[46] In the case before us, we are satisfied that the inherent disclosure of the production of crystalline losarton potassium in the description of the 414 patent specification particularly Example 316 Part D, as proven by the experimental results of DW6 and DW7, constitutes inherent disclosure which is sufficient to support claim 7 of the patent. The appellant has not adduced any evidence to show that the losarton potassium obtained by DW6 and DW7 using the method of Example 316 Part D would not produce losartan protassum in crystalline form.

[47] It is DW6's testimony that the specification of the 414 patent, when read together as a whole, suggests to a person skilled in the art that the crystalline form of losartan potassium can be made. In other words, any person of ordinary skill in the art would find that the disclosure in the 414 patent specifications, particularly, the method disclosed by Example 316 Part D is sufficient to enable him to produce crystalline losartan potassium in claim 7. Such disclosure clearly complies with the requirement of reg 12(1)(c) and reg 13(1) of the 1986 Regulation.

[48] We are satisfied that in respect of claim 7, of the 414 patent, the descriptions and specifications have disclosed the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art ie a skilled person in the art can readily perform the invention over the area claim in claim 7. Therefore, we are satisfied that reg 12(1)(c) and reg 13(1) of the 1986 Regulations have been complied with.

[49] In respect of claim 8, it must be noted that claim 8 is directed to a pharmaceutical composition. It is not directed to a preparation of a carrier and losartan in combination with hydrochlorothiaside ('HTCZ'). Claim 8 in effect comprises of the following elements, namely a pharmaceutical composition; a pharmaceutical suitable carrier; losartan or pharmaceutically acceptable salt of losartan; and hydrochlorothiaside.

[50] Example 89 of the 414 patent discloses, inter alia, a method of

preparation of losartan (at p 167, lines 1-26 of the patent). Pages 300–201 of the 414 patent, containing Example 316 Part C discloses another method of preparation of losartan. Therefore element relating to 'losartan' has been sufficiently described in the description.

[51] Example 316, Part D at pp 301–302 of the 414 patent discloses a method of preparation of a potassium salt of losartan. Again, an element relating to 'pharmaceutically acceptable salt of losartan', such as potassium salt of losartan, has been sufficiently described.

[52] There is also a description to the effect that 'This invention relates to novel substituted imidazoles. The invention also relates pharmaceutical compositions containing the novel imidazoles and pharmaceutical method using them, alone and in conjunction with other drugs especially diuretics' (see p 1 of the 414 patent — lines 5–10). A person of ordinary skill in the art based on his common general knowledge and upon reading the 414 patent specifications would know that losartan belongs to the group of chemical compounds referred to as imidosoles.

[53] Lines 27–30 of the same page state that 'Administration of a compound of this invention with a diuretic such as hydrochlorothiazide enhances the antihypertensive effect of the compound'. Losartan belongs to the group of chemical compounds referred to as 'substituted imidazoles'. Thus the above statements provide support for the elements of pharmaceutical composition, pharmaceutical suitable carrier and hydrochlorothiaside ('HTCZ') in claim 8.

[54] The said 414 patent's description also states, at p 19, lines 3–4, that 'Pharmaceutically suitable salts include both the metallic (inorganic) salts and organic salts; alist of which is given in Reminpton'. This further supports the elements of pharmaceutical composition and hydrochlorothiaside (HCTZ).

[55] There is also a statement to the effect that 'According to the present invention there are pharmaceutical compositions comprising a diuretic, a pharmaceutically suitable carrier and an angiotensin II blocking antihypertensive imidazole' at p 19, lines 34–36 and p 6, lines 1–2 of the 414 patent's description. This also provides support for element pharmaceutical composition and element pharmaceutical suitable carrier.

[56] On the above position the court is of the view that the description in claim 8 of the 414 patent has sufficiently and adequately describes or teaches the invention and support the invention. There is no other evidence adduced by the appellant to rebut the finding on this issue. The learned trial judge had correctly accepted the respondent's evidence and agreed with the respondent's submission on this point.

[57] The validity of the respondent's 414 patent was also challenged by the appellant on the ground that claims 7 and 8 of the 414 Patent do not comply with s 30 of the Patents Act 1983 and reg 27A of the 1986 Regulations in that claims 7 and 8 are not present in any corresponding patents of the respondent in the prescribed countries or convention namely Australia, United Kingdom, United States of America and the European Patents (EP) Convention. The basis of the appellant contentions is that the 414 patent was granted based on modified substantive examination which requires the 414 patent to conform to a corresponding patent granted in one of the prescribed countries or convention. The appellant contended that the amendment of the 414 patent (in particular, the inclusion of claims 7 and 8 in its granted form) has gone beyond the scope allowable by the Patens Act 1983 and the 1986 Regulations.

[58] Section 30 of the Patents Act 1983 and reg 27A of the 1986 Regulations deal with the substantive examination and modified substantive examination of patent in the process of obtaining a patent. The prosecution process of the patents between 1989 (ie the date of filing of the 414 patent) until 1998 (ie the date of grant of the 414 patent) was explained by DW2, the Head of the Patents Formality Section and the Senior Assistant Registrar of MylPO.

[59] According to DW2, at the relevant period of between 1989 to 1998, the substantive examination entailed an examination as to whether the subject invention (in this case, the 414 patent) has met the patentability criteria of s 11 of the Patents Act 1983 ie whether the invention was new, involved on inventive step and was industrially applicable. However, from 1 August 1995 onwards, (with the new amendment to the Patents Act 1983) there were introduced two types of substantive examination vide the new ss 29A and 30(1) of the Act.

[60] Section 29A(2) of the amendment, provides:

> If a patent or other title of industrial property protection has been granted to the applicant or his predecessor in title in a prescribed country outside Malaysia or under a prescribed treaty or Convention for an invention which is the same or essentially the same as the invention claimed in the application, the applicant may, instead of requesting for a substantive examination, request for a modified substantive examination.

[61] Apparently, under s 29A, there are now two types of examinations available:

(a) the standard substantive examination; and

(b) the modified examination procedure.

The rationale of modified examination procedure is to ensure that by bringing the Malaysian application for patent registration into conformance with the granted application in the prescribed countries or convention, the Malaysian application will be granted without the need to repeat the substantive examination. However, even after the amendment, the Registrar of Patent in Malaysia may by virtue of s 29A(4) request for any information or supporting documents including any search results relating to any foreign application to assist him in the substantive examination of the Malaysian application.

[62] According to DW2's testimony, when the 414 patent was first filed on 6 January 1989, it initially contained 75 claims. A first substantive examination report was issued on 23 May 1996, whereby it was discovered the existence of prior published documents. The applicant did not provide any comment. Upon subsequent examiner's examination, the registrar issued a clear report dated 4 January 1997. According to DW2, the registry regards the first substantive report as an adverse report.

[63] On 12 Mac 1997 the applicant filed amendments to the application which comprised of the submission of an amended set of claims numbering (1)–(29) which were claims that were similar to the then corresponding EP Patent Application No 89100144.8 (granted as EP 324 377) under the European Patents Convention. The said amendments were in order and in accordance with the legal and procedural requirements at that time. They were examined substantively for inventiveness and patentability; more particularly the amended claims 7 and 8 were examined for their inventiveness and novelty. The acceptance of the amendments vide the registry's letter dated 6 March 1998 shows the fact of such acceptance and compliance of the amendments with the requirements of the Patents Act 1983.

[64] The respondent has adduced sufficient evidence to show that the 414 patent has undergone the required substantive examination under the law and regulations at the material times. The said 414 patent has been examined based on its very own merits; it was not examined on the basis of there being in existence the corresponding EP324277.

[65] The mode of modified substantive examination as introduced under s 29A of the amendment to the Patents Act 1983, and reg 27A of the 1986 Regulations, which took advantage of other foreign corresponding application in the prescribed countries or the European Patent Convention was not available in Malaysia during the prosecution of the 414 patent between 1989 and 1998. As such there is no requirement for the respondent to undergo such modified substantive examination. Regulation 27A of the 1986 Regulations which stipulates how a request for modified substantive examination could be made by the patent applicant only came into force on 16 August 2006. That

being the case, it matter not if the granted 414 patent contains additional claims (claims 7–8) different from that of the EP 324377 patent. Consequently, the appellant's objection on this point is wholly unsustainable and must be rejected. The grounds of Appeal No 19–21 in the memorandum of appeal must fail.

[66] On the issue of validity of the 414 patent, particularly claims 7 and 8, we are in full agreement with the learned trial judge that claims 7 and 8 of the said 414 patent are at all material times, valid and subsisting; and therefore are enforceable against any third party including the appellant. Thus, under s 36 of the Patents Act 1983, the respondent as the patent owner shall have exclusive rights upon the grant of the patent. Such exclusive rights include the right to license, sell, and manufacture or otherwise deal with the patent continues so long as the patent subsists on the registrar and the annuity payments are made.

The respondent's presence in court

[67] The appellant's complaints relating to grounds 3–6 of the memorandum of appeal, in essence can be summarised as follows:

(a) there was no representative from the respondent company in court; and the respondent was not physically present to give testimony before the learned judge;

(b) the appellant alleged that in truth the party defending the action was Merck & Co; and if Merck & Co had wanted to defend the action, it should have applied to add itself as a party to the action; and

(c) regardless of the above the learned judge had gone on to hold that the named respondent, EI Du Pont De Nemours and Company, was properly before him defending the action and to prosecute the counterclaim;and to that extent, the learned judge had erred in law and in fact.

[68] The present case is a civil case, where the court decides based on the evidence adduced during trial on the balance of probabilities. Under s 101 of the Evidence Act 1950 the person who asserts the existence of any fact must prove the fact exists. Section 102 of the same Act stipulates that the burden of proof in a suit or proceeding lies on that person who would fail if no evidence at all were given on either side. What the respondent needs to do (as the defendant to the present claim) is to enter appearance within time and to be represented by counsel to handle the proceeding on its behalf; to file the necessary statement of defence and counterclaim as well as other follow-up documents to get the matter ready for trial. All these had been duly done by the respondent.

[69] For the purpose of trial, the respondent needs to adduce evidence, either by calling its witnesses to testify in court and to tender documentary evidence in order to prove its defence and counterclaim. In this case the respondent had called seven witnesses to testify on its behalf.

[70] Section 118 of the Evidence Act 1950 provides that all persons shall be competent to testify unless the court considers that they are prevented from understanding the questions put to them or from giving rational answers to those questions by tender age, extreme old age, disease or any other cause of the same kind. Section 120(1) of the Evidence Act 1950 states that in all civil proceedings the parties to the suit shall be competent witnesses. Thus, a party to a suit may be competent to give evidence but he may not be compelled to do so. Section 134 of the Evidence Act 1950, makes it clear that no particular number of witnesses shall in any case be required for the proof of any fact. The evidence of every witness is to be judged on its own merits.

[71] There is no law to say that a party to a civil proceeding must personally attend court and give evidence to support its claim or counterclaim. The respondent may, at its own discretion call any number of witnesses whose evidence are relevant to prove its defence and counterclaim. In this case the respondent had called the following seven witnesses to satisfy its evidential requirements:

(a) DW1 ('Siti Aida') — an officer from the National Pharmaceutical Control Bureau (NPCB); whose evidence is important to support the respondent's contention that the statutory rights upon the patent owner and the requirements for his authorisation to work the patent are not made subject to any other pieces of legislation;

(b) DW2 ('Puan Shamsiah bt Kamaruddin') — an officer at the Intellectual Property Corporation of Malaysia (MyIPO) who heads the Patents Formality Section; her evidence was to explain the applicable examination procedures of patent applications during the year 1989 (ie the date of filing the 414 patent) until 1998 (ie the date of grant of the 414 patent). This is important to rebut the appellant's contention that the 414 patent was granted based on modified substantive examination;

(c) DW3 (''Abu Bakar Hussein') — was an investigator employed to purchase the appellant's product in question, COVANCE tablets from AA Pharmacy located at No 38, Lucky Garden, Bangsar, Kuala Lumpur. His evidence is necessary to establish (together DW5) the existence of the appellant's activities with regard to the infringement of the said product;

(d) DW4 ('Ewe Kheng Huat') — is the Managing Director of MSD Malaysia, a Malaysian branch of Merck Sharp & Dohme (IA) Corp, the licensee of the respondent's 414 patent; his evidence is to establish the

business presence and activities surrounding the respondent's 414 patent; and to show the extent of the damages suffered by the respondent as a result of the appellant's infringing activities;

(e) DW5 ('Dr Andy Kusumo') — was a senior project scientist at Merck Sharp & Dohme Corp; he was the recipient of COVANCE 50 mg and 100 mg purchased by DW3; he had conducted experiments on these COVANCE 50 mg and 100 mg; and the results showed that losartan potassium peaks appear in the powder of COVANCE 50 mg and 100 mg and this, infringing claims 7 and 8 of the respondent's 414 patent;

(f) DW6 ('Prof Jo Klaveness') — was the CEO and President of Drug Discovery Laboratory As, Oslo, Norway; CEO of DDL Biopharma As, Oslo, Norway; he was also a professor in the Medicinal Chemistry School of Pharmacy, University of Oslo; his evidence is to show that any person of ordinary skill in the art would find that the disclosure in the 414 patent specification, particularly the method disclosed by Example 316 Part D is sufficient to enable him as a person of ordinary skill in the art, to produce crystalline losartan potassium in claim 7; and

(g) DW7 ('Len Chyall') — is a director at the SSCI division of Aptuit, also performed the exact experiment as DW6 in his laboratory at Aptuit; his evidence has the same effect as that of DW6's evidence ie any person of ordinary skill in the art would find that the disclosure in the 414 patent specification particularly disclosed by Example 316 Part D is sufficient to enable him to produce crystalline losartan potassium in claim 7. (Both DW6 and DW7's evidence show that such disclosure complies with the requirement of regs 12(1)(c) and 13(1) of the 1986 Regulations; and thus rebutting the appellant's claim that claims 7 and 8 were not supported by the description of the 414 patent).

[72] Both DW6 and DW7 were called as expert witnesses on behalf of the respondent. Their evidence was the most relevant for the purpose of defending the invalidity claim against the respondent's 414 patent. How the respondent decides to defend its case is a matter of its own discretion. At the end of the day, the court should assess the evidence presented by both parties in totality. By calling seven witnesses and tendering all the relevant documents during trial, the court is satisfied that this is not a case of the respondent having abandoned its pleading as impliedly suggested by the appellant. The learned judge had aptly considered all the relevant considerations and this court is in full agreement with His Lordship's finding on the issue:

> To my mind, the effect of all these provisions is simply this: the defendant has a complete discretion, subject to the provisions of the EA and the Rules of the High Court 1980, as to the preference and selection of the witnesses to be called at the trial and the documents to be produced to prove all facts essential to its case. Therefore, it matters not if the representative of the defendant was or was not present in court

during the course of the trial. But the important point which requires to be kept in mind in the present case is this: the defendant has called seven witnesses and tendered numerous exhibits to defend the validity of the 414 patent and to prove its counter claim for infringement against the plaintiff.

[73] On the above considerations, we are of the view that the appellant's ground of appeal on this particular issue is clearly without merit and must also fail. The totality of the evidence testified by all the seven witnesses for the respondent throughout the trial as well as all the documents tendered by the respondent has on the balance of probabilities enable the respondent to establish its defence to the appellant's claim and to establish its case in the counterclaim against the appellant. The learned judge was correct in his decision to dismiss the appellant's claim and to allow the respondent's counterclaim. The fact that the respondent's own representative did not attend court to give evidence personally was not in any way fatal to the respondent's case.

[74] At the outset of the hearing at the Court of Appeal, learned counsel for the appellant informed the court that the appellant was pursuing only on two issues namely:

(a) on procedural issue ie the respondent has failed to appear in court either to defend the action or to prosecute the counterclaim; and

(b) on the validity of the 414 patent ie claims 7 and 8 are invalid and therefore the 414 patent is also invalid and unenforceable against any other party.

[75] It appears that the appellant was not pursuing the appeal on the ground of 'infringement' that relates to the respondent's counterclaim against the appellant. The appellant's outline of written submissions as well as the oral submissions in court touches nothing on the issue of 'infringement' of the patent in question. So, for the purpose of the present appeal, we take the stand that the appellant was not pursuing the issue of 'infringement' of the patent in the respondent's counterclaim as well as other issues not raised during the appeal before us.

CONCLUSION

[76] We are in full agreement with the findings and grounds of decision of the learned judge. We find no reason to disturb them. The learned judge had aptly considered all the relevant considerations relating to the matter before him and has come to a correct decision. We therefore dismiss the appeal with costs of RM50,000 to the respondent. We affirm the decision of the learned

judge both on the main claim as well as the counterclaim. We also make an order that the deposit is to be paid to the respondent an account of costs.

Appeal dismissed with costs and High Court's decision affirmed.

Reported by Ashok Kumar